UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* ADAM HART,

Plaintiff-Relator,

v.

MCKESSON CORP., *et al.*,

Defendants.

No. 15-Civ-0903 (RA) (JLC)

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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INTRODUCTION

As this Court clearly set forth in May, to survive a motion to dismiss, Relator's allegations must "support a finding that McKesson knew *this particular course of* [at-issue] *conduct was unlawful*." ECF No. 155 ("Opinion"), at 29 (emphasis added). For the reasons provided in McKesson's opening brief, Relator does not and cannot sufficiently allege that McKesson knew that providing the Margin Analyzer ("MA") and Regimen Profiler ("RP") as alleged was unlawful. Faced with this fact, Relator's Opposition is, at its core, an improper motion to reconsider the Court's scienter standard. But, contrary to Relator's protestations, the cases Relator cites, some of which were explicitly considered by the Court in dismissing the First Amended Complaint ("FAC"), reaffirm the scienter standard the Court articulated.

Relator's Opposition also fails to address the many instances where the SAC relies on conclusory allegations and unreasonable inferences. This fatal flaw dooms not only Relator's allegations of scienter, but also his argument that he has adequately pled a nationwide scheme under Federal Rule of Civil Procedure 9(b). The Court should thus dismiss the Second Amended Complaint ("SAC"), including all state False Claims Act ("FCA") claims,[1] with prejudice.

ARGUMENT

I. Relator Cannot Satisfy the Scienter Standard.

A. Relator Attempts to Lower the Scienter Standard Adopted By This Court.

In its decision dismissing Relator's FAC, the Court adopted a clear scienter standard under the Anti-Kickback Statute ("AKS")—"to satisfy the AKS' scienter requirement, Hart must

[1] Relator argues that McKesson has not requested dismissal of the state claims asserted in the SAC. This is untrue. McKesson's Motion to Dismiss the SAC (ECF No. 171) seeks dismissal of the *entire* SAC with prejudice. *Id.* at 1. Relator's state law claims are subject to the same pleading requirements as his federal claims and should be dismissed for the same reasons—both with respect to scienter and Rule 9(b). The Court previously took this approach when granting McKesson's Motion to Dismiss the FAC in its *entirety* for failure to adequately plead scienter.

plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful." Opinion at 28. Since the Court's decision, the Second Circuit has confirmed that the scienter standard requires "a voluntary, intentional violation of a known legal duty" and for the defendant to "know[] that his conduct is illegal." *Pfizer, Inc. v. United States Dept. of Health and Human Servs.*, 42 F.4th 67, 77 (2d Cir. 2022). Relator acknowledges that he must meet this standard, but nonetheless attempts to lower its requirements by arguing that willfulness can be shown where the defendant "(1) knows that the AKS prohibits the provision of anything of value as an inducement, yet (2) engages in intentional conduct to provide things of value as inducements anyway." ECF No. 180 ("Opp."), at 5. The Court has already rejected this view, expressly stating that general knowledge of the AKS coupled with behavior that potentially violates the AKS is *not* sufficient to plead AKS scienter. Opinion at 29 ("awareness of the requirements of the AKS and the general unlawfulness of inducements" coupled with "facts to support the conclusion that the tools may constitute 'remuneration'" were not enough to "support a finding that McKesson knew *this particular course of conduct was unlawful*") (emphasis added). And contrary to Relator's claims, neither case law nor common sense supports him.[2]

1. The Cases Relied on by Relator Do Not Support Relator's Scienter Standard and Compel Dismissal of the SAC.

By requiring only that a defendant knows generally of the AKS and engaged in conduct that allegedly violates it, Relator's proposed standard seeks to eliminate the AKS' requirement that the defendant *knew* its particular course of conduct was unlawful. This gutting of the

[2] Indeed, some of the cases Relator relies on including *Teva*, *Pasqua*, *Mittal*, and *Bilotta*, were either raised by Relator or cited by the Court on the Motion to Dismiss the FAC. These cases do not support Relator. For example, in *Mittal*, the court decided that the evidence established "actual knowledge of the AKS," such that any error by not instructing the jury that the defendant knew of and intended to violate the AKS was harmless, not whether the defendant acted willfully as a matter of law. Opinion at 23–24. The jury was instructed the defendant had to know his conduct was unlawful, and had found that to be the case. 36 F. App'x 20, 21–22 (2d Cir. 2002).

scienter standard is not supported by the cases Relator cites. Rather, in each of those cases, the allegations supported a plausible inference that the defendant knew that its conduct was illegal. Thus, these cases affirm the Court's articulation of the standard and compel the SAC's dismissal.

First, many of the cases Relator relies on cite allegations that defendants were provided and considered at the highest levels detailed information about how the at-issue conduct violated the AKS, which the courts found sufficient to allege that the defendants knew their conduct was unlawful. *See, e.g.*, *United States v. Teva Pharm. USA, Inc.*, 560 F. Supp. 3d 412, 421–22 (D. Mass. 2021) (concluding Teva knew the law prohibited its conduct because law firm advised that specific conduct raised legal issues); *United States v. Genesis Glob. Healthcare*, No. 4:18-cv-128, 2021 WL 4268279, at *12 (S.D. Ga. Sept. 20, 2021) (citing allegations that founders discussed AKS with investors and were told by an investor, who backed out of the investment, that scheme violated the AKS); *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020) (citing allegations that company's VP received articles discussing the illegality of the at-issue conduct and knew similar conduct was unlawful). These cases directly support the scienter standard the Court articulated. *See* Opinion at 29–30 (citing *Mallinckrodt*, *Teva*, and other cases). And the SAC contains no allegations that McKesson received and ignored advice regarding the legality of the specific at-issue conduct.

Second, in other cases Relator cites, scienter was supported by other allegations that plausibly alleged that the defendant knew that the AKS prohibited the specific at-issue conduct. For example, the cases include allegations that (1) defendants engaged in conduct that violated internal policies that forbid the specific course of action as unlawful under the AKS; and/or (2) the specific conduct was widely recognized by the industry as illegal. *See, e.g.*, *United States v. Teva Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2019 WL 1245656, at *9–12 (S.D.N.Y. Feb. 27,

2019) (internal guidance prohibited the specific at-issue conduct based on AKS); *United States ex rel. Bilotta v. Novartis Pharm. Co.*, 50 F. Supp. 3d 497, 518–21 (S.D.N.Y. 2014) (alleging that defendants repeatedly violated internal policies and industry guidance about speaker programs designed to prevent AKS violations); *United States ex rel. Pasqua v. Kan-Di-Ki LLC*, No. CV 10–965–JST (RZx), 2012 WL 12895229, at *5 (C.D. Cal. June 18, 2012) (illegality of specific conduct was known "throughout the health care industry" at the time).

Here, by contrast, Relator alleges only that McKesson held general AKS trainings, SAC ¶¶ 8, 157–59, not that it had specific policies warning that provision of the MA or RP as alleged violated the AKS. Moreover, the SAC includes no allegation that the industry widely recognized that the provision of tools like the MA and RP in the manner alleged by the SAC violated the AKS. To the contrary, Relator's SAC cites open advertising of McKesson's MA and RP tools without industry response, *see, e.g.*, *id.* at ¶¶ 130, 167, and attaches documents that reference tools provided by other companies, *see* ECF No. 176-5 at 17 (analyzing competitors' business tools). In addition, case law and OIG guidance has recognized that provision of certain types of tools and support do not necessarily implicate the AKS. *See, e.g.*, Opinion at 17–20 (citing OIG guidance, advisory opinions, and cases recognizing, for example, that companies may provide certain support services without implicating the AKS).[3]

Third, Relator cites several other cases in which there was no question that the defendant knew that the specific alleged conduct at issue—a straightforward provision of money with the

[3] The 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003), acknowledges that some companies may provide support services and that at least some such services may not implicate the AKS. Similarly, case law and OIG Advisory Opinions show that though a product or service may have value, it does not necessarily violate the AKS. *See, e.g.*, OIG Adv. Op. No. 12-20 (concluding software products linked to medicines made by the manufacturer didn't violate AKS); OIG Adv. Op. No. 00-10 (providing information regarding insurance coverage and reimbursement did not violate the AKS).

singular purpose to induce patient referrals—violated the AKS. *See, e.g.*, *United States v. Mittal*, 36 F. App'x 20 (2d Cir. 2006) (defendant received cash payments for referrals); *United States v. Nowlin*, 640 F. App'x 337 (5th Cir. 2016) (defendant agreed to refer clients in exchange for commissions); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (defendant admitted that "his relationship with the Hospital had turned into receiving payment for patient referrals"). These cases support that there must be plausible allegations the defendant knew the illegality of its specific conduct, not the standard for which Relator advocates (i.e., that general knowledge of the AKS and conduct that allegedly violates the AKS is sufficient).

Relator insists that his scienter formulation is "common sense," but in reality, it would undermine the AKS' rigorous scienter requirement. *See* Opinion at 22–25. Allegations that a defendant knew generally of the AKS and engaged in conduct that allegedly violates the AKS do not show that the defendant knew that its specific conduct was unlawful. *See id.* at 29–30. Put differently, just because one knew of the AKS, does not mean that they knew that their conduct violated it. This is especially true in situations like this one where there is no allegation that the specific conduct has been clearly recognized as unlawful by internal policies, industry guidance, and case law. In these situations, without more, the Court should not assume that the defendant knew its conduct violated the AKS, otherwise the AKS' willfulness requirement will collapse into the lower standard Relator previously sought and this Court rejected. Opinion at 26–28.

B. <u>The SAC Relies on Conclusory and Implausible Allegations of Scienter.</u>

The allegations in the SAC fail to raise a plausible inference that McKesson knew its conduct was unlawful. Because Relator's SAC fails, despite having the benefit of this Court's clear articulation of the scienter standard, the SAC should be dismissed with prejudice.

First, Relator is incorrect that McKesson's Motion "focuses narrowly" on Relator's "'additional' allegations of scienter," and that other of the SAC's allegations sufficiently allege

scienter. Opp. at 11. As discussed in the Motion, *see* ECF No. 172, Section I.C., the purported allegations of scienter throughout the SAC are conclusory or are the "types of allegations the Court previously rejected." *Id.* at 15. For instance, as previously discussed, "identifying a policy that plausibly violates the AKS and alleging that a defendant had a general awareness of the laws . . . is not enough to establish scienter." Opinion at 30. Yet, Relator relies on allegations that individuals received AKS compliance training and provided the MA and RP to customers. *See, e.g.*, SAC ¶¶ 8, 53, 157–59. The SAC also relies on conclusory statements that individuals knew the tools had value and violated the AKS. *See id.*, ¶¶ 52, 160–63. Unlike the cases discussed in Section I.A, Relator does not bridge the gap between general AKS knowledge and knowledge that the specific conduct was unlawful. Thus, his allegations do not plausibly allege scienter.

Second, Relator overstates his allegations about his supposed newly-recalled conversations regarding compliance concerns with the MA and RP. Relator attempts to align his allegations in the SAC with those in *Fitzer*, in which relator filed a third amended complaint alleging that the vice president of sales "debate[d]" the legality of the quota scheme and said he would raise it with the CEO. Opp. at 14 (citing *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-CV-00668-SAG, 2021 WL 5840874, at *3–4 (D. Md. Dec. 9, 2021)). Notably, the *Fitzer* court contrasted those allegations with the insufficient allegations in the second amended complaint, stating "the allegation (in the SAC) that Relator told Allergan it was violating the AKS provides no facts that relate to Allergan's state of mind." *Fitzer*, 2021 WL 5840874, at *4. Here, Relator's SAC allegations do not even rise to the level of the allegations rejected in Fitzer's second amended complaint. At best, Relator alleges that he raised general compliance concerns to his supervisor during a compliance training meeting. *See* SAC ¶ 164. These allegations are distinguishable from cases in which specific complaints about unlawful conduct

were raised to the highest levels within companies and those complaints were considered and disregarded. *See supra* Section I.A.1. Like the rejected *Fitzer* second amended complaint, one general statement made to a regional manager that "current sales practices . . . violated the compliance policies," SAC ¶ 164, says nothing about McKesson's state of mind and fails to sufficiently allege scienter.[4]

Third, Relator continues to rely unavailingly on the email in which Mr. Kaminsky forwarded multiple lengthy U.S. Oncology ("USON") documents that hardly mention MA or RP stating "you didn't get this from me."[5] SAC ¶ 160. Contrary to Relator's Opposition, McKesson does not argue that there are many interpretations of the email, one of which satisfies the scienter pleading standard. *See* Opp. at 15. Instead, it argues that there are many potential explanations for this email, but there is *no* support for the unwarranted inferential leap Relator asks this Court to make to conclude that this document plausibly shows that McKesson knew that its provision of MA and RP to Open Market customers was unlawful. ECF No. 172, at 11–13.

Fourth, Relator attempts to manufacture scienter by alleging that McKesson's website no longer refers to the MA. Even assuming that the MA is no longer promoted on McKesson's website, Relator has no allegations to support the unwarranted inference that this is because McKesson believes its conduct was unlawful. Nor does this have any relevance to McKesson's scienter during the relevant time period many years ago, during which time, according to

[4] Similarly, Relator's allegations of two conversations with employees that the provision of the MA and RP was "unethical and wrongful" and "inappropriately exploit[ative]," but not unlawful or violating a known legal duty, fail to adequately plead scienter. *See* SAC ¶¶ 165–66.

[5] Again, Relator tries to attribute scienter to McKesson's Open Market division through documents created by the separate USON division, though he expressly omitted USON from his allegations. As Judge Cott noted with respect to this precise document, "the relationship between U.S. Oncology's valuation of the tool for its own customers and Open Market's use of the tool strikes me as tenuous." ECF No. 128, Hr'g Tr. (Aug. 11, 2021), at 16:8–16:11.

Relator's allegations, McKesson widely promoted these tools. *See* Opinion at 30.

Finally, Relator's Opposition continues to harp on baseless allegations of document destruction. These allegations are spurious and lack a good faith basis. Relator does not dispute that Judge Cott found no indication that McKesson improperly destroyed documents. *See* ECF No. 144, Hr'g Tr. (Jan. 12, 2022), at 5:17–20 ("I don't think there is enough in the record . . . to suggest that there was some improper destruction of these documents"); *id.* at 21:22–22:4 ("As presented [any document destruction] seems to have occurred in the normal course[;] . . . companies like McKesson rightfully engage in appropriate destruction in the regular course . . ."). Instead, Relator ignores Judge Cott's ruling as not binding on his ability to raise these rejected allegations for another purpose. The Court should not credit these allegations.[6]

II. Relator's Nationwide Fraud Allegations Fail to Satisfy Rule 9(b) Because They Require the Court to Draw Unsupported Inferences.

Relator urges the Court to make an unreasonable link between Relator's vague assertions of a nationwide scheme and the list of practices in the SAC's appendices. Relator asserts that the SAC describes "top-down instructions" for the MA and RP, and that McKesson salespeople used MA and RP "as inducements pursuant to this strategy . . . ." Opp. at 17–18. However, the documents referenced in the SAC (such as at ¶ 129) only generally discuss McKesson's "value-added services." Relator attempts to cover up this deficiency with the conclusory statement that MA and RP "*are* these value-added services," *id.* at 20, but Relator's actual allegations do not

[6] Even if the Court were to credit these allegations, they are insufficient because the facts alleged do not raise a plausible inference that McKesson destroyed documents to conceal conduct it knew was unlawful. This distinguishes Relator's allegations from those in the cases he cites. *See Burciaga v. GEO Grp., Inc.*, No. 3:12cv2059-L-WVG, 2017 WL 10605270 (S.D. Cal. Feb. 28, 2017) (finding evidence at summary judgment that the "Defendant destroy[ed] records *to keep them from* ACA auditors" sufficient to meet FCA's scienter standard) (emphasis added); *S.E.C. v. Suterwalla*, No. 06–cv1446 DMS (LSP), 2008 WL 9371764 (S.D. Cal. Feb. 4, 2008) (alleging that the plaintiff destroyed documents protected by an injunction to conceal fraud).

support this conclusion. *See, e.g.*, SAC ¶ 121 (referring to a document that lists MA and RP as two of nearly two-dozen "Products, Programs, and Services"). Relator also asserts that the list of practices in the SAC's appendices "demonstrat[e] the nationwide reach of McKesson's kickback scheme." Opp. at 18. But nowhere does the SAC provide sufficient detail about how McKesson perpetuated the alleged scheme with these practices. Without connecting the practices to particular fraudulent conduct, Relator has not satisfied Rule 9(b).

Relator implements this same circular logic to the exhibits attached to McKesson's Motion. For example, regarding the email located at Ex. 5, ECF No. 160-5, Relator concedes that it does not necessarily support the inference that McKesson adopted the discussed approach, but asserts that other portions of the SAC "allege with particularity that McKesson did exactly what this presentation had directed." Opp. at 19. Relator asserts that SAC ¶¶ 123–27 contain the missing allegations, but these paragraphs describe vague messages delivered at a training event, not particular fraudulent conduct carried out throughout the country. Allegations of information provided to sales personnel nationwide are the type of vague information held insufficient to establish nationwide fraud in *United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 730 (N.D. Ill. 2020). In fact, Relator does not meaningfully contest that the SAC fails to describe specific details about how the alleged fraud occurred with the newly listed practices. Instead, he incorrectly asserts that such detail is unnecessary to satisfy Rule 9(b) because he alleges a nationwide strategy. Opp. at 18–20. This is not so. *See Suarez*, 503 F. Supp. 3d at 731 ("because Relator has alleged fraud with particularity in just one state, his FCA claims are limited to conduct that occurred in Florida").[7] Despite Relator's plea that the SAC alleges a

[7] Relator misinterprets McKesson's argument as depending on the causation standard for false claims resulting from an AKS violation. Opp. at 21–23. This is not so and the Court need not determine this standard to decide McKesson's Motion. While the Second Circuit has not

nationwide fraud when "viewed collectively," Opp. at 19, such allegations are not in the SAC.

Finally, Relator's allegations post-2015 are insufficient to satisfy Rule 9(b). Relator states that the SAC includes allegations "through at least 2019," and that an appendix includes dates "through at least 2017." Opp. at 25. Relator does not identify specific allegations in the SAC post-2015, much less to the present. Relator argues that he has pled a continuing fraud by "outlining the time period over which [the fraud was] executed." *United States ex rel. El-Amin v. George Washington Univ.*, No. Civ.A. 95-2000(JGP), 2005 WL 485971, at *9 (D.D.C. Feb. 25, 2005). But *El-Amin* held that relators are not "absolved of their obligation under Rule 9(b) to plead at least *some* instances of alleged fraud with particularity[.]" *Id.* Relator's conclusory allegations that McKesson engaged in fraud years after his employment, and an appendix listing customers who *may* have received an MA in a single quarter in 2016 or 2017, fail this standard. *See United States ex rel. Frey v. Health Mgmt. Sys.*, Inc., No. 3:19-CV-0920-B, 2021 WL 4502275, at *15 (N.D. Tex. Oct. 1, 2021) (restricting time period of claims for lack of allegations outside of that time period). At minimum, Relator's post-2015 claims should be dismissed.

CONCLUSION

The Court should dismiss the SAC in its entirety with prejudice.

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weighed in on this standard, the Eighth Circuit in *United States ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 831 (8th Cir. 2022) recently held that the words "resulting from" in the AKS, "create[] a but-for causal requirement between an anti-kickback violation and the 'items or services' included in the claim." Relator cannot meet this standard, which the Eighth Circuit correctly decided, and seeks to avoid it. But neither can he satisfy any other standard regarding what is required to satisfy 9(b). Even *Teva*, on which Relator chiefly relies, acknowledges that relators must show a "a link" between an AKS violation and a particular patient and claim. *Teva*, 2019 WL 1245656, at *24. And in nationwide FCA cases, courts have held that relators must link alleged kickbacks to false claims actually submitted by identifying "representative examples" of "fraudulent transactions." *United States ex rel. Suarez v. AbbVie, Inc.*, No. 15 C 8928, 2019 WL 4749967, at *10–11 (N.D. Ill. Sept. 30, 2019). Relator has failed to do so. If the Court believes determining the causation standard is necessary at this time, McKesson respectfully requests additional space to brief the issue Relator raised.

Respectfully submitted,

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